Revisiting Industrial Applicability and Utility Criteria: AI's Role in the Inventive Process and Postmodern Human-Centric IP Development.

Alia Kahwaji

Abstract

Examining industrial applicability and utility standards in patent law remains a cornerstone of the patent system frameworks. While scholarly discourse has extensively debated other patentability criteria, such as novelty and inventive step tests across jurisdictions, the specific impact of advancements in AI tools on industrial applicability remains largely unexplored. This gap is critical because AI tools, such as predictive analytics, can challenge traditional interpretations of utility tests by blurring the lines between credible potential applications as set in case law, and hypothetical conjectures.

This paper investigates how AI's capabilities affect the thresholds for deeming patent claims "plausible" or "speculative" under industrial applicability tests. This study evaluates legal frameworks in the European Patent Convention, the United Kingdom, and the United States, analysing case law, statutory provisions, and examination guidelines. Key cases, such as *Human Genome Sciences v. Eli Lilly*, are used to assess current standards through comparative legal and socio-economic approaches critically. The findings highlight the need for a nuanced reinterpretation of industrial applicability and utility standards to account for AI's predictive capabilities. The study advocates for harmonised, stricter legal frameworks that safeguard against speculative patents while strengthening related criteria such as patent eligibility and morality as interpreted in Articles 53(a) of the EPC. This research also situates the discussion within a postmodern framework, emphasising a shift from rigid, traditional patent standards to a more responsive, human-centric approach that reflects contemporary societal and technological complexities introduced by AI.

Contents

1. INTRODUCTION

The European requirement for industrial applicability has significantly shaped modern patent systems.[1] Originating from the Strasburg Convention of 1963, Article 57 of the European Patent Convention (EPC) established harmonised patentability criteria, specifying that patents must be novel, involving an inventive step, and capable of industrial application.[2] Similarly, the UK's definition of a patentable invention dates back to the 1623 British Statute of Monopolies,[3] which granted privileges for any "manner of new manufacture." Courts subsequently interpreted practical application, or utility, as central to patent eligibility.[4]

In the U.S., the utility requirement aligns with the EPC's industrial application standard, emphasising practical usefulness.[5] Rooted in the Constitution,[6] The U.S. utility criterion has evolved through legislation and judicial interpretations, with courts,[7] particularly the Court of Appeals for the Federal Circuit (CAFC), clarifying the concept of "useful."[8] This requirement excludes purely intellectual innovations or abstract ideas without industrial applicability, ensuring clear boundaries for patentable subject matter and avoiding overlaps with other forms of intellectual property rights.[9]

The industrial applicability and utility requirements are central to patent law but are interpreted and applied differently across jurisdictions. The European Patent Office (EPO)'s Technical Board checks for industrial applicability, emphasising practical,[10] reproducible use in industrial practice,[11] requiring a concrete benefit rather than speculative or vague claims.[12] In contrast, the U.S. system requires inventions to demonstrate 'substantial, specific, and credible' utility, whereas even inventions that meet European industrial applicability standards may fail due to the higher bar set for utility.[13] Moreover, the UK's interpretation of industrial applicability has evolved, as seen in *Human Genome Sciences v. Eli Lilly*,[14] where the threshold for establishing industrial applicability was lowered to allow plausible, but not fully established or tested, benefits and applications of inventions.

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[1] See Marta Díaz Pozo, The European requirement of industrial application in Patenting Genes, (Edward Elgar Publishing, 2017) accessed Nov 12, 2024.
[2] Ibid.
[3] Statute of Monopolies 1623.
[4] Ibid.
[5] 35 U.S. Code § 101.
[6] Constitution of the United States 1787, art 1, s 8 (Powers of Congress).
[7] Application of *Nelson and Brenner v Manson* show differing interpretations of what qualifies as "useful" for inventions with uncertain applications, especially in research.
[8] DL Zuhn, 'DNA Patentability: Shutting the Door to the Utility Requirement' (2000) 34 *John Marshall Law Review* 973.
[9] Utility and industrial applicability are interchangeable throughout this paper.
[10] Case T 0870/04 BDP1 *Phosphatase/MAX-PLANCK* of EPO Technical Boards of Appeal 2005 and case T 0898/05 *Hematopoietic receptor/ZYMOGENETICS* of EPO Technical Boards of Appeal 2006.
[11] Ibid.
[12] Coupled with common general knowledge (citing EPO Boards of Appeal cases T 0898/05, T 0604/04).
[13] A Gallochat, 'The Criteria for Patentability: Where are the Boundaries?' (WIPO Conference on the International Patent System, Geneva, 25–27 March 2002).
[14] *Human Genome Sciences v Eli Lilly* (2011) UKSC 51.

Over the past century, the significance of industrial applicability in European patent law has declined, particularly compared to the stricter utility standards in the U.S.[15] The broad interpretation of the criteria has made it an easy test to satisfy.[16] Despite its historical significance alongside novelty and inventive step requirements, [17] industrial applicability has received limited scholarly attention in light of AI advancements. In parallel, recent literature has conceptualised an emerging paradigm of human-AI collaborative innovation, with scholarly discourse extensively examining how these approaches challenge traditional patent law doctrines.[18] While academic discussion has largely focused on AI's impact on the Inventive Step/Non-obviousness test, a critical gap remains in addressing how AI tools affect industrial applicability criteria.

With venture capital firms investing billions in generative AI (GenAI) solutions and predictions that over 30% of new drugs and materials will be systematically discovered using AI by 2025,[19] the patent system appears ill-equipped to filter out frivolous or premature inventions. Indeed, AI's sophisticated data analysis and application simulation capabilities offer enhanced precision for industrial applicability predictions, particularly within complex scientific domains. This advancement introduces a need to rethink the industrial applicability framework while raising broader implications for patent system theory and policy. This paper explores how AI, when perceived as a standard tool in inventive processes and R&D activities, can fundamentally impact the efficiency in assessing industrial applicability requirements.

While artificial intelligence is unlikely to replace the expertise of human researchers in the near future, it demonstrates significant potential to augment scientific creativity in different ways.[20] For example, by automating patent analysis and prior art searches, algorithms can systematically navigate vast data sets, revealing unexplored conceptual domains and potential industrial applications for any invention. Essentially, AI can extend inventors' imaginative capabilities beyond conventional human constraints, presumed under the *status quo*

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[15] M W Haedicke and H Timmann (eds), *Patent Law: A Handbook on European and German Patent Law* (CH Beck, Hart and Nomos 2014) 125.

[16] The broad interpretation is derived from various sources, including case law such as the Human Genome case and Article 1(3) of the Paris Convention, which mandates that industrial property should be interpreted in its broadest sense. This provides a guiding standard for the European Patent Office (EPO) in interpreting the term "industry" under Article 57 of the EPC.

[17] C Wadlow, 'Utility and Industrial Applicability' in T Takenaka (ed), *Patent Law and Theory* (Edward Elgar 2008) 359. See also J Phillips, 'The English Patent as a Reward for Invention: The Importation of an Idea' (1982) 3 *The Journal of Legal History* 71.

[18] See for example Y Hao, 'The Rise of "Centaur" Inventors: How Patent Law Should Adapt to the Challenge to Inventorship Doctrine by Human-AI Inventing Synergies' (2024) 104 *J Pat & Trademark Off Soc'y* 71; M Mariani, Y K Dwivedi, 'Generative Artificial Intelligence in Innovation Management: A Preview of Future Research Developments' (2024) 175 *Journal of Business Research* 114542.

[19] The Research VP for Technology Innovation at Gartner, B Burke as cited in M Mariani and Y K Dwivedi, 'Generative Artificial Intelligence in Innovation Management: A Preview of Future Research Developments' (2024) 175 *Journal of Business Research* 114542.

[20] I M Cockburn, R Henderson, S Stern, 'The Impact of Artificial Intelligence on Innovation' in *The Economics of Artificial Intelligence* (University of Chicago Press 2018) 115–146.

criteria.[21] For instance, in pharmaceutical research, AI tools can predict therapeutic uses for compounds based on data patterns without requiring experimental confirmation. One example is the upheld patent in *Human Genome Sciences v. Eli Lilly.*[22] The patented Neutrokine-α gene was discovered through computational data mining and bioinformatics techniques. The patent was upheld even when no experimental data from *in vivo* or *in vitro* studies supported the proposed function. Although the case laid a set of standards for industrial applicability, it actively waived the need for the industrial application to be tested and verified as a condition to meet the criteria. The decision was influenced by the BioIndustry Association (BIA)'s argument that bioscience companies may face critical timing issues for patent filing and warned that a stricter interpretation of industrial applicability would hinder UK companies' ability to secure early investment.

Beyond pharma, similar challenges can emerge in other sectors. Take, for example in the field of advanced engineering materials; an AI system analysing composite materials predicted that a specific carbon fibre-polymer matrix combination could a) provide superior strength-to-weight ratios for aerospace applications, b) exhibit self-healing properties under certain stress conditions, and c) demonstrate enhanced electromagnetic shielding capabilities. In this example, the predictions were based on molecular dynamics simulations and machine learning analysis of existing composite databases but lacked physical prototype testing or real-world stress analysis. Furthermore, the patent application included only computational predictions based on molecular modelling and theoretical calculations, lacking the material's physical synthesis or performance testing. Suppose this hypothetical invention passes other patentability tests and satisfies the industrial applicability test, which can be an easy task under the criteria *status quo*. In that case, the inventor will gain a patent monopoly over plausible uses of the invention that have not yet been verified. While the AI's predictions are more sophisticated than the early bioinformatics techniques used for Neutrokine-α, they raise similar fundamental concerns.

To address this scenario, this paper doctrinally examines whether AI-generated predictions, even when based on advanced computational methods, can make it easier to satisfy industrial applicability tests even for abstract inventions that generally fall under the patentability excluded list. It also explores the necessary reforms for the criteria to address this problem. The analysis begins by revisiting the rationale for a flexible versus strict interpretation of industrial applicability, followed by a critical assessment of industrial applicability tests across three jurisdictions: the EPO, the UK, and the US. Finally, the paper evaluates the implications of AI tools and develops policy recommendations for patent examination frameworks.

[21] See for example, Y Hao, 'The Rise of "Centaur' Inventors: How Patent Law Should Adapt to the Challenge to Inventorship Doctrine by Human-AI Inventing Synergies' (2024) 104 *J Pat & Trademark Off Soc'y* 71.
[22] *Human Genome Sciences v Eli Lilly* (2011) UKSC 51

2. FLEXIBLE VERSUS STRICT INTERPRETATIONS OF INDUSTRIAL APPLICATION

Academic literature and case law highlight a tension between strict and flexible approaches to industrial applicability. On the one hand, a flexible interpretation of industrial applicability where speculative industrial applications are acceptable to satisfy the criteria aligns with the logic stating that commercial inventors rarely invest in R&D for inventions without practical or financial utility in mind. Conversely, such flexibility does not account for strategic behaviours or follow-on inventions. Indeed, while minor incremental improvements with speculative applications may meet the requirement of industrial applicability, they can temporarily block more major or fully developed innovations.[23]

This debate is further complicated by the utilitarian principles underpinning patent systems.[24] A flexible interpretation that emphasises purely utilitarian principles, encouraging innovation in the classical modernistic view. This perspective views patents as instruments for economic progress, aiming to enhance society through a) maximising access to new and useful goods, services, and technical information arising from inventive efforts and b) promoting the highest levels of economic activity derived from the production, circulation, and further development of these goods and services information.[25] Such an interpretation is likely to assume that AI tools accelerate innovation and equate this acceleration with progress.

2.1. Arguments for a Flexible Industrial Applicability Test

Some academic discourse presents arguments advocating for a broader interpretation of industrial application criteria in patent law, such as the one set by *Human Genome v Eli Lilly*.[26] The central argument posits that potential utility should suffice for patent protection, particularly in software, chemistry, and biotechnology fields.[27] Several key considerations support this argument: firstly, the inherent difficulty in identifying inventions entirely devoid of potential utility;[28] secondly, the unpredictable nature of scientific discovery, where unintended applications may prove valuable in unforeseen contexts; and thirdly, the risk of knowledge suppression if strict utility requirements impede early-stage disclosure.[29] Furthermore, drawing from Mirabel's perspective, it is suggested that even seemingly non-viable inventions contribute to the public knowledge base without impeding access to knowledge and future innovation[30] while maintaining the potential for future commercial success. Other scholars went as far as advocating for redundancy of the utility test, arguing that utility does not fulfil a unique role in patentability and that its functions are effectively

[23] R S Eisenberg and R P Merges, 'Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences' (1995) 23 *AIPLA Quarterly Journal* 1.
[24] For example, see M Schankerman and F Schuett, 'Patent Screening, Innovation, and Welfare' *The Review of Economic Studies*, Volume 89, Issue 4, July 2022, 2101–2148; S H Haber and N R Lamoreaux (eds), *The Battle over Patents: History and Politics of Innovation* (New York, 2021; online edn, Oxford Academic, 21 October 2021).
[25] G Dutfield and U Suthersanen, *Global Intellectual Property Law*, Second Edition (Edward Elgar Publishing Limited, 2020) 153.
[26] *Human Genome Sciences v Eli Lilly* (2011) UKSC 51
[27] E P Mirabel, 'Practical Utility Is a Useless Concept' (1986) 36 *American University Law Review* 811.
[28] Ibid.
[29] Ibid.
[30] T Cook, *Pharmaceuticals, Biotechnology and the Law* (2nd edn, Lexis Nexis) 150-151.

addressed by ensuring robust novelty, non-obviousness[31] and enabling disclosure, which guarantees that patented inventions benefit the public.[32]

2.2. Arguments for a Strict Industrial Applicability Test

On the contrary, other scholars present strong arguments for implementing strict standards for industrial applications. The arguments comprise three pillars: fundamental patent policies, practical utility considerations, and philosophical foundations. Patent policies fundamentally support strict interpretation of industrial applicability standards to maintain basic research accessibility and prevent premature monopolisation of early-stage inventions.[33] The utility argument emphasises that flexible standards might inadvertently reward premature patenting of incompletely developed innovations, potentially impeding scientific progress.[34] Furthermore, given that industrial applicability represents the invention's public value and social utility, a balanced patent bargain between the inventor and the public needs to impose strict usefulness requirements to meet.[35] This approach can be interpreted to suggest that a stricter approach to industrial applicability may serve both; encouraging innovation and fulfilling public interest by ensuring social utility.[36]

2.3. Reflections on The Two Approaches

While a flexible approach may encourage early-stage innovation by maintaining the current *status quo* and providing protections for more inventions as facilitated by AI tools, it also risks monopolising premature inventions with limited proven utility. In such cases, it can be argued that prioritising non-trivial industrial applications could prevent stifling breakthrough inventions.[37] This can be addressed through multiple upgrades to the patentability criteria. Whether or not industrial applicability criteria should evolve to demand higher thresholds will likely depend on how follow-on inventions are addressed within the patent system policy.[38] Furthermore, despite the notion of the social utility of inventions as a patenting standard, there is evidence of disconnection between societal needs and the goals of private actors,[39] coupled with minimal

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[31] On this, E P Mirabel refers to confusion and overlap between 'how to use' and 'useful'.

[32] S B Seymore, 'Making Patents Useful' (2014) *Minnesota Law Review*.

[33] S C Pippen, 'Dollars and Lives: Finding Balance in the Patent Gene Utility Doctrine' (2006) 12 *BUJ Sci & Tech L* 193.

[34] As the analysis of cases revealed in R S Eisenberg and R P Merges, 'Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences' (1995) 23 *AIPLA Quarterly Journal* 1.

[35] See generally on the social value for inventions S Jasanoff, *The Ethics of Invention: Technology and the Human Future* (WW Norton & Company, New York 2016).

[36] For full discourse on the arguments for and against stricter Industrial Applicability criteria, see M Díaz Pozo, 'Chapter 3: The European Requirement of Industrial Application: The Requirement of Industrial Application' in *Patenting Genes* (Edward Elgar Publishing 2017).

[37] R S Eisenberg and R P Merges, 'Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences' (1995) 23 *AIPLA Quarterly Journal* 1.

[38] Ibid.

[39] See D Rodrik, 'Private or Public: What's Really Driving Technological Innovation?' (*World Economic Forum*, 19 August 2020) <www.weforum.org/stories/2020/08/democratizing-innovation/> accessed 25 January 2025.

attention paid to non-utilitarian interpretations of patent value as implemented in the patentability criteria tests and technology development trajectories.[40]

Conversely, a stricter interpretation of industrial applicability standards ensures inventions provide credible and tested utility before being patented but may stifle innovation. Thus, a balanced regulatory approach must address these dynamics by refining industrial applicability standards to incorporate technological developments and broader socio-economic objectives, such as preventing speculative monopolies and ensuring social value for inventions.

2.4. A Moral Case for Exclusion? Rethinking Ethicality Boundaries

It is submitted that measuring social utility or empirically identifying a stricter test for industrial applicability and usefulness is difficult.[41] However, this does not negate the need to ask a missing important question regarding the social and moral value an invention ought to hold and provide. Applying this principle to data-induced inventions, it can be argued that inventions created or facilitated by AI may not always address an existing societal demand but instead create new demands through their perceived utility. For instance, inventions like Amazon's "one-click buy"[42] or Self-driving vehicles exemplify a case of 'induced demand',[43] where companies generated technologies to satisfy a demand that was never expressed.[44] This raises ethical concerns regarding whether the existing framework allows for patents on inventions that do not demonstrably benefit society. It may also safeguard inventions that are not just trivial or experimental but could ultimately disadvantage the public from a socio-economic perspective.

This paper argues that the conventional understanding of utility and industrial applicability in patent law can be significantly enhanced by incorporating nuanced ethical evaluations derived from the doctrine of moral and public order exceptions to patentability.[45] By integrating broader societal considerations into the utility assessment, patent systems could more comprehensively evaluate the utility of inventions within not only the technical context of the invention but also within a socioeconomic context. Such an approach can contribute to tackling induced demand cases and closing the gap between societal needs and the

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[40] B Ribeiro and P Shapira, 'Private and Public Values of Innovation: A Patent Analysis of Synthetic Biology' (2019) 49 *Research Policy* 103875 <www-sciencedirect-com.uea.idm.oclc.org/science/article/pii/S0048733319301945> accessed 24 January 2025.

[41] Or as Arnold J in *Novartis v Medimmune*: 'In particular, it is unclear precisely what is meant by "specified (or identified) in the wording of the claims".

[42] One high-profile example was granted in 1999. The patent was licensed to Barnes & Noble to settle a patent suit and, despite widespread scepticism as to its validity, ran to full term without its validity ever being resolved by the courts; see M Schankerman and F Schuett, 'Patent Screening, Innovation, and Welfare', *The Review of Economic Studies*, Volume 89, Issue 4, July 2022, 2101–2148.

[43] I Batur and others, 'The Induced Demand Implications of Alternative Adoption Modalities of Automated Vehicles' (ROSA P Home) <www.rosap.ntl.bts.gov/view/dot/77641> last accessed 27 December 2024.

[44] See D Rodrik, 'Private or Public: What's Really Driving Technological Innovation?' (*World Economic Forum*, 19 August 2020) <www.weforum.org/stories/2020/08/democratizing-innovation/> accessed 25 January 2025.

[45] As in Article 53(a) of the European Patent Convention. The exclusions under art 53 EPC prohibit things which could otherwise be regarded as inventions for reasons of public policy/morality (exceptions to patentability), as opposed to the other exclusions, which are things deemed to be non-inventions under art 52 EPC.

incentivised R&D activities carried out by private actors. The traditional industrial applicability criteria, which primarily focus on technical functionality and predicted commercial potential, could be expanded to include an ethical dimension that assesses whether an invention can be made or used and whether its potential implementation aligns with fundamental human-centred values and societal well-being and needs.

Such an integrated approach to patent examination would allow for more robust scrutiny of the utility of inventions through a multi-layered lens, challenging the primary utilitarian justification of patents within a postmodern technological and legal landscape. This perspective challenges traditional deterministic views of technology, often seeing technological progress as linear or inevitable.[46] Conversely, it emphasises the social and cultural dimensions of technological development.[47] In industrial applicability terms, this means a stricter interpretation where assessing usefulness means combining a verification for actual technical utility with a postmodern critique filter of linear technological progress.[48] Building on this, such an approach to reform industrial applicability should ensure a robust verification mechanism that not only requires non-speculative utility but also incorporates a broader definition of utility beyond technical meaning, addressing inventions' moral and societal dimensions.

It is noted that the contemporary legal framework and policy approach around industrial applicability, utility and exclusion based on public order and morality varies between jurisdictions. To examine this proposed theory against the legal *status quo*, the following section provides a critical analysis of three jurisdictions and provides insights into reform opportunities.

3. CRITICAL ANALYSIS OF THE LEGAL FRAMEWORK

Historically, the patent system was designed to incentivise the development of practical, useful inventions and technical knowledge and thereby promote social progress by supporting new industries and industrial development.[49] Industrial applicability criteria are implemented in national legislation, case law, and patent office examination guidelines and manuals.

This section analyses how the regulatory frameworks of the UK, the European Patent Office, and the United States address speculative and abstract inventions, focusing on industrial applicability and exclusions based on public order and morality. Although a comprehensive comparative analysis of industrial applicability and utility requirements is beyond the scope

[46] See on this generally, S Johnson and D Acemoglu, Power and Progress: Our Thousand-Year Struggle Over Technology and Prosperity, (Basic Books 2023).
[47] See FM Collyer, 'Technological Invention: Post-Modernism and Social Structure' (1997) 19 Technology in Society 195, available at <https://www.sciencedirect.com/science/article/abs/pii/S0160791X96000644> accessed 24 January 2025.
[48] Ibid.
[49] J Pila, *The Requirement for an Invention in Patent Law* (Oxford University Press 2010) 8.

of this paper, it provides insights into the intersection of these criteria with the evolving role of AI in inventive processes.

3.1. The European and The United Kingdom Approaches

The industrial applicability of an invention extends beyond the potential for industrial production as the criterion requires a demonstration of a 'useful purpose'.[50] The legal framework, including the European Patent Convention (EPC)[51] and the EPO examination guidelines,[52] The Patents Act 1977,[53] and the UK Manual of Patent Practice,[54] establishes that an invention must exhibit a 'practical application' or provide a 'concrete benefit'.[55] The critical assessment hinges on the invention's potential use being 'reasonably credible' or 'plausible' rather than 'merely 'speculative'[56]; however, the criteria do not mandate proof of actual experimentation or implementation; instead, it necessitates establishing a credible potential for industrial applicability.[57] In theory, this approach provides flexibility while maintaining a threshold of substantive utility, ensuring that patent protection is not granted to hypothetical or entirely theoretical innovations. This approach was applied in *Icos Corporation*[58] by the Opposition Division at the European Patent Office (EPO) to deny patent protection for a purified and isolated polynucleotide encoding for the amino acid sequence of the V28 protein.[59] While the applicant listed several predicted uses for the claimed protein, the problem was that these uses were based on the protein's predicted function as a receptor and not on tested functions.[60]

In *Human Genome Sciences v. Eli Lilly*,[61] a more pro-industry approach was followed in the UK. The case concerned the validity of a patent that claimed the nucleotide sequence of the human Neutrokine-α gene, which encodes for a novel protein.[62] L Neuberger upheld the

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[50] *Chiron v Murex* (1996) RPC 535, 607: the Court of Appeal held that the requirement that the invention can be made or used "in any kind of industry," so as to be "capable of industrial application," carries the connotation of trade or manufacture in its widest sense, whether or not for commercial profit. The Court went on to hold that industry does not "exist in that sense to make or use that which is useless for any known purpose."

[51] European Patent Convention, Article 57 Industrial applicability.

[52] EPO, *Guidelines for Examination*, Part G – Chapter III-1, Industrial application, March 2024.

[53] Section 4(1), The Patents Act 1977 (as amended).

[54] Intellectual Property Office, Manual for practice, section 4(1) available at <www.gov.uk/guidance/manual-of-patent-practice-mopp/section-4-industrial-application>, last accessed 24 December 2024.

[55] T 870/04 *Max-Planck/BDP1 phosphatase* (2006) EPOR 14, (6), (7), (21); T 898/05 *Zymogenetics/Hematopoietic cytokine receptor* (2007) EPOR 2, (2), (4), cited with approval by Supreme Court in *Human Genome Sciences v Eli Lilly* (2011) UKSC 51, (2012) RPC (6) 102, (107

[56] *Human Genome Sciences v. Eli Lilly* (2011) *UKSC* 51, (2012) *RPC* (6) 102, (107), (149); See also *Warner-Lambert v Generics* (2018) *UKSC* 56, (2018) *RPC* (21) 831.

[57] *Human Genome Sciences v. Eli Lilly* (2011) *UKSC* 51

[58] European Patent Office, 'Decision of the President of the European Patent Office dated 3 June 2002 concerning the filing of priority documents' (2002) OJ EPO 293 <www.epo.org/en/legal/official-journal/2002/06/p293.html> accessed 10 March 2025.

[59] As cited in L Bently and others, *Intellectual Property Law* (6th edn, OUP 2022) ch 17: the UK IPO said that it will follow *Icos Corporation* (2002) OJ EPO 293: UK Patent Office, *Biotechnology Examination Guidelines* (September 2002) 33–35.

[60] Which aligns with Guidelines of the US utility requirement under US patent law on 5 January 2001stating that, for an invention to have requisite utility (which is similar to industrial application), there must be a 'specific, substantial and credible' use. See *Manual of Patent Examining Practice*, §2107/II(A)(3)(ii).

[61] *Human Genome Sciences v Eli Lilly* (2011) UKSC 51

[62] *Eli Lilly v Human Genome Sciences Inc* (2011) UKSC 51, (2012) RPC (6) 102, following *Human Genome Sciences/Neutrokine* (T 18/09, 21 October 2009).

validity of the HGS patent even though the lower courts have invalidated it based on the fact that it was found to be "speculative and did not give rise to an immediate concrete benefit".[63] The patent also included predictions about therapeutic activities in the gene.

Three notable considerations of this case make it tightly relevant to the discussion around AI. First, the Neutrokine-α gene discovery was accomplished through data-mining techniques, which are computer-assisted sequences involving bioinformatics and sequence homology analysis, rather than traditional experimental laboratory methods. Second, the gene was identified as belonging to the TNF ligand superfamily, a group of cytokine proteins integral to intercellular communication in immune and inflammatory processes. Third, the gene's proposed functional description was fundamentally derived from its structural similarity to other TNF ligand superfamily members without substantive empirical validation. Critically, the patent's functional claims were not supported by direct experimental evidence from biological studies but instead represented a speculative inference based on the gene's taxonomic classification, assuming that membership in a specific genetic category implied shared functional characteristics across the group.[64]

Turning to the exception from patentability, the EPC contains an express public order and morality-based patent eligibility bar. Article 6(a) of the EU Biotech Directive and EPC Article 53 states: "European patents shall not be granted in respect of: (a) Inventions the publication or exploitation of which would be contrary to 'order public' or morality ...."[65] However, this does not include any judgements as to the invention's social benefit or value. While this legislative approach is promising, European patent law's terms "order public" and "morality" remain vague and narrowly defined.[66] The European approach supports the patenting of uncertain and ambiguous technologies in resource-concentrated fields such as biotech owing to their dependence on venture capital to be fully developed and commercialised,[67] while requiring that opponents of a patent bear a heavy burden of demonstrating that the patent would offend morality or public policy, including by presenting "conclusive evidence" that its risks to public policy outweigh its benefits.[68]

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[63] Ibid; This comes after Lewison LJ commented that 'It is clear from the specification that the patentee had no real idea what neutrokine- α or its antibodies would do if introduced into a living creature...'.

[64] As discussed in L Bently and others, *Intellectual Property Law* (6th edn, OUP 2022) Ch 17 at 552.

[65] Unlike in the US, the patent laws of the European Union and many European countries contain specific provisions that exclude immoral inventions from patentability. See E Bonadio, Patents and Morality in Europe, in *Diversity In Intellectual Property* 149; See J C Lai, Myriad Genetics and the BRCA Patents in Europe: The Implications of the US Supreme Court Decision, 5 *University of California, Irvine School of Law review* 1041, 1074 (2015); also, D M Gitter, Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law, 19 *Berkeley Journal of International Law* 1, 13 (2001).

[66] J Crockett, Morality: An Important Consideration at the Patent Office, *California Law Review*, February 2020, Vol 108, No 1 (February 2020), 267-304; see also Pila J, Adapting the Ordre Public and Morality Exclusion of European Patent Law to Accommodate Emerging Technologies (2020) 38 *Nature Biotechnology* 555. Similar terms are listed in the UK Patents Act 1977, Section 1(3).

[67] *Human Genome Sciences, Inc. v. Eli Lilly* (2011) UKSC 51 (99-100) (Lord Neuberger).

[68] T356/93 *Plant Genetic Systems/Glutamine Synthetase Inhibitors* (Opposition by Greenpeace) (1995) EPOR 357 for Technical Board of Appeal 3.3.4, 21 February 1995, 366 -372.

3.2. The United States Approach

Since the passage of the first Patent Act in 1790, an inventor must demonstrate that his invention is useful to secure a patent.[69] The modern U.S. utility requirement derives from two other sources: congressional legislation[70] implementing a constitutional mandate 'to promote the progress of science and useful arts'[71] and federal court decisions interpreting the meaning of the word 'useful' in the Constitution and the implementing legislation.[72] Although usefulness appears to be a less demanding requirement, as explained below, it is possible for a claimed invention to pass the industrial applicability test in Europe but fail the analogous test in the U.S.

The U.S. Supreme Court in *Brenner v. Manson* required that utility must be substantial and the invention must be fully developed.[73] The court stated in this context that a patent is not a hunting license. It is not a reward for the search but compensation for its successful conclusion.[74] The United States Patent and Trademark Office (USPTO) 's 2001 reformulation of utility standards established a three-level assessment framework. Developed primarily in response to challenges presented by gene patenting, specificity, substantiality, and credibility have become a cornerstone of U.S. patent utility evaluation.[75] The utility requirement is a low hurdle to overcome for most inventions.[76] According to USPTO Utility Examination Guidelines, it is sufficient to meet the requirement if a patent application recites at least one "specific, substantial, and credible" use for an invention.[77] The requirement is satisfied easily. Patentees need only to disclose one specific use of the invention to satisfy utility, yet they gain control over all potential uses, including those not yet discovered or developed. This can create a disparity between what is disclosed and what is protected, prompting calls to restrict patent protection to the uses explicitly detailed in the application.[78]

Turning to the social value, in principle, patent law's utility requirement is perceived as an adaptable instrument for excluding socially undesirable inventions without explicit moral prescriptions.[79] This was established in the *Lowell v. Lewis* decision,[80] as explained, "[a]ll that the law requires is that the invention should not be frivolous or injurious to the well-being,

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[69] J Timothy Meigs, 'Biotechnology Patent Prosecution in View of PTO's Utility Examination Guidelines' (2001) 83 JPTOS 451.
[70] United States Code, Title 35, Section 101, see MPEP § 2107 for guidelines for the examination of applications for compliance with the utility requirement of 35 USC 101.
[71] Article 1 (Section 8) of the US Constitution.
[72] D L Zuhn, 'DNA Patentability: Shutting the Door to the Utility Requirement' (2000) 34 J Marshall L Rev 973.
[73] *Brenner v. Manson* 383 US 519 (1966).
[74] Ibid.
[75] USPTO, 'Utility Examination Guidelines', Federal Register 66(4); 1092–99, 2001; ICOS Corp/Novel/V28 seven transmembrane receptor (2002) 6 OJEPO 293; Aeomica Inc BL O/286/05, see S Thambisethy, 'Legal Transplants in Patent Law: Why Utility is the New Industrial Applicability' (2009) 49 *Jurimetrics Journal* 195.
[76] M A Bagley, 'Patent First, Ask Questions Later: Morality and Biotechnology In Patent Law' (2003) <www.scholarship.law.wm.edu/wmlr/vol45/iss2/3> last accessed 10 March 2025.
[77] Examination Guidelines for the Utility Requirement, 66 Fed Reg 1092, 1098 (Jan 5, 2001); The Utility Examination Guidelines are instructions to be used by USPTO examiners when assessing the patentability of a claimed invention.
[78] This highlights the close relation between Industrial Applicability and other patentability procedures; See L Bently and others, *Intellectual Property Law* (6th edn, OUP 2022) Ch 17.
[79] M A Bagley, 'Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law' (2003) 45(2) *William and Mary Law Review* 469.
[80] *Sawyer v Whipple* 15 F Cas 1018 (CCD Mass 1817) (No 8,568).

good policy, or sound morals of society.[81] Therefore, the word 'useful' is incorporated into the act in contradistinction to mischievous or immoral."[82] This, followed by a landmark ruling by the Court of Appeals for the Federal Circuit in *Juicy Whip v. Orange Bang,*[83] proved influential in effectively terminating the moral utility doctrine. The court's dismissal of arguments for applying moral utility criteria to invalidate a patent on a deceptive innovation marked a definitive shift in patent jurisprudence.

With these rulings, it can be argued that the U.S. morality and public order exclusions was capped at a lower level;[84] the USPTO's Manual of Patent Examining Procedure does not mention morality or ethics anywhere in its section on utility. Instead, the manual cites *Juicy Whip* and states: "A rejection under 35 U.S.C. 101 for lack of utility should not be based on grounds that the invention is frivolous, fraudulent or against public policy."[85]

3.3. Reflections on the Three Legal Frameworks

In the three jurisdictions discussed, it is apparent that the notions of "industrial applicability" and "utility" are broad and, at least in part, overlap.[86] However, the analysis reveals critical inconsistencies in how jurisdictions conceptualise utility and industrial applicability. The current frameworks will struggle to address predicted applications or applications that are based on AI simulation, which means that more abstract ideas might make their way to the patent pool without being empirically tested benefits, which can also touch on the list of excluded subject matters and create significant legal and ethical challenges within the patent system frameworks. This gap is especially noticeable in fields like biotechnology, pharmaceuticals, and AI, where inventions can be identified as potentially patentable at early research stages.

Furthermore, the EPO approach to Article 53(a) was described as overly restrictive and critically unresponsive to the regulatory challenges posed by emerging technologies. [87] By constraining public participation in the patent system, this approach undemocratically entrenches the interpretive power of patent officials and inventors,[88] necessitating urgent systemic reconsideration.

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[81] P Lee, 'Innovation in the Service of Society' (2014) 104 *Boston University Law Review* 695.
[82] Ibid at 1019 (emphasis added).
[83] *Juicy Whip, Inc v Orange Bang Inc* 185 F3d 1364, 1367 (Fed Cir 1999).
[84] *Lowell v Lewis* 15 F Cas 1018 (CCD Mass 1817) (No 8568) ('for instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention'); see also M A Bagley, 'Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law' (2003) 45 *William and Mary Law Review* 469.
[85] US Patent & Trademark Office, *Manual of Patent Examining Procedure*, 706 Rejection of Claims (R-07 2015) <www.uspto.gov/web/offices/pac/mpep/s706.html> accessed 27 December 2024; see also *Juicy Whip Inc v Orange Bang Inc* 185 F3d 1364, 1367–68 (Fed Cir 1999).
[86] WIPO, *The Practical Application of Industrial Applicability/Utility Requirements Under National and Regional Laws*, Informal paper prepared by the International Bureau (April 2001) <www.wipo.int/scp/en/meetings/session_5/pdf/scp5_inf.pdf> accessed 27 December 2024.
[87] J Pila, 'Adapting the *Ordre Public* and Morality Exclusion of European Patent Law to Accommodate Emerging Technologies' (2020) 38 *Nature Biotechnology* 555
[88] P Drahos, *The Global Governance of Knowledge: Patent Offices and Their Clients* (CUP 2010) 285–317, cited in J Pila, 'Adapting the *Ordre Public* and Morality Exclusion of European Patent Law to Accommodate Emerging Technologies' (2020) 38 *Nature Biotechnology* 555.

In the U.S., such filtering is partly addressed through subject matter eligibility determined by case law but not effectively under §101, which no longer includes the moral utility doctrine.[89] The Juicy Whip case motioned a shift in U.S. patent law from factoring in moral utility to assess whether inventions might harm society to a purely utilitarian focus on substantial and practical utility. This change disregards the broader societal impact of inventions, placing greater emphasis on market-driven considerations.[90]

Finally, the analysis reveals that the core issue is not merely definitional but structural; existing patent frameworks fundamentally fail to assess the genuine social value and long-term implications of technological innovations.[91] By focusing narrowly on technical utility as confined to the knowledge of the person skilled in the art, these systems risk enabling patent protection for inventions that may technically meet current criteria but potentially harm societal interests. This necessitates not only adopting a stricter interpretation of the criteria mandating empirical validation rather than predictive use, but a paradigm shift from a purely technical assessment of utility to a more holistic, progressive evaluation that considers broader ethical and social dimensions of innovation.

4. POLICY RECOMMENDATIONS

The legal *status quo* sets a low threshold through broad interpretation for industrial applicability and limited channels for intervention based on morality and public order, which, when combined with AI's predictive and simulation capabilities, risks exacerbating existing issues in the patent system and creating new problems.

This paper argues that morality and eligibility considerations should extend beyond public order concerns to address utility and industrial applicability more fundamentally, particularly in *ex-ante* examination as the most logical stage for addressing a moral and consequential sense of utility.[92] In other words, the proposed approach aims to introduce greater certainty in patent applications by emphasising actual rather than plausible utility, establishing democratic channels to challenge inventions' risks and utility and emphasising innovations' social value. Furthermore, the paper stresses a need to address innovation as an integral, socially embedded phenomenon that is both stimulated by and fulfilling societal needs. While it was argued in the scrutinised approaches that other institutions address such concerns, the analysis reveals that patent law is well-positioned to tackle the addressed issues, given that

[89] J Crockett, 'Morality: An Important Consideration at the Patent Office' (2020) 108 *California Law Review* 267.
[90] Ibid.
[91] On the social value of inventions see B Ribeiro and P Shapira, 'Private and Public Values of Innovation: A Patent Analysis of Synthetic Biology' (2019) 49 *Research Policy* 103875 <www-sciencedirect-com.uea.idm.oclc.org/science/article/pii/S0048733319301945> accessed 24 January 2025.
[92] For full discussion in scholars in favour and against this approach, see J Crockett, 'Morality: An Important Consideration at the Patent Office' (2020) 108 California Law Review 267.

patent examiners already engage in ethical and moral assessments during technical evaluations.[93]

The current patent system's economic utilitarian approach inadequately evaluates innovation's societal impact.[94] Financial metrics like patent numbers provide limited insights into technological progress.[95] A postmodern human-centric approach demands deconstructing traditional economic assumptions, focusing on preventing frivolous patents and monopolistic biases.[96] The proposed reforms to the framework advocate for a stricter interpretation of industrial applicability that balances innovation incentives with societal benefits. This requires engaging diverse stakeholders, moving beyond top-down technology policies,[97] and ensuring AI-generated predictions and simulations translate into tangible social value.[98] Ultimately, the goal is a collaborative human-AI relationship that prioritises human creativity and well-being, with AI serving as a complementary tool for meaningful technological advancement. [99]

[93] S Thambisetty, 'Understanding Morality as a Ground for Exclusion from Patentability under European Law' (2002) 12 *Eubios Journal of Asian & International Bioethics* 48, 41.
[94] J Osei-Tutu, 'A "Human Development" Approach to Intellectual Property Law' in I Calboli and M L Montagnani (eds), *Handbook of Intellectual Property Research: Lenses, Methods, and Perspectives* (OUP 2021; online edn, Oxford Academic, 23 September 2021).
[95] Ibid.
[96] See for example B M Frischmann, 'Capabilities, Spillovers and Intellectual Progress: Toward a Human Flourishing Theory for Intellectual Property' (2017) 14 *Review of Economic Research on Copyright* 30.
[97] A Anthony, 'AI Expert Marietje Schaake: "The Way We Think about Technology Is Shaped by the Tech Companies Themselves"' (*The Guardian*, 30 November 2024) <www.theguardian.com/technology/2024/nov/30/marietje-schaake-tech-coup-save-democracy-silicon-valley> accessed 27 December 2024.
[98] It is notable here that absent changes to the disclosure requirement there is no traceability available to track AI tools uses in the inventive process and patent filing.
[99] European Digital Rights and Principles, <https://digital-strategy.ec.europa.eu/en/policies/digital-principles> accessed 28 December 2024.